510(k) Summary

K072777

JAN 24 2008

1. Submitter Information:

Company: CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia USA 30097

Contact Person: Martina Heim, PhD, RAC
Senior Regulatory Specialist, Global Regulatory Affairs
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Date Prepared: 21 September 2007

2. Device Name:

- Common Name: Soft Contact Lens
- Trade/Proprietary Name: CIBA Vision® (nelfilcon A)
- Classification Name: Daily Wear Soft Contact Lens
- Device Classification: Class II [21 CFR 886.5925 (b) (1)]

3. Predicate Device:

CIBA Vision's Focus® DAILIES® (nelfilcon A) soft contact lenses have been selected as predicate devices for the modified CIBA Vision® (nelfilcon A) lenses. CIBA Vision obtained FDA 510(k) clearance for (nelfilcon A) lenses for daily wear on November 27, 1996 (K963487).

4. Description of Device:

The nelfilcon A lens material is 69% water and 31% nelfilcon A polymer (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide). The lenses are tinted from edge to edge for visibility purposes with the color additive copper phthalocyanine (CuP).

Nelfilcon A lens designs currently include spherical, toric, and multifocal in the following parameter ranges:

- Power Range: -20.00D to +20.00D
- Center Thickness: 0.010 mm for -3.00D spherical (varies with power)

Lenses have the following properties:

- Refractive index: 1.38
- Light transmittance: approximately 96 %T
- Water content : 69% by weight
- Oxygen permeability 26 barrer
  measured at 35°C (single point Dk-Polarographic method)

Lenses are supplied sterile in sealed blister-packs containing buffered saline. The compatibility and package integrity of the blister-pack packaging system has been demonstrated and successfully used for other CIBA Vision marketed lens products, and packaged lenses are effectively steam sterilized in a validated autoclave. Blister-pack containers are labeled with the lens parameters, lot number and product expiration date. The expiration date has been established through stability studies that have assessed the chemical stability of the lens and package integrity (ability to maintain sterility). Shelf-life studies are ongoing to establish and extend the labeled expiration date.

5. Indications for Use:

CIBA Vision® (nelfilcon A) Spherical and Toric One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes.

CIBA Vision® (nelfilcon A) Progressives One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia in not-aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single-use daily disposable wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

6. Description of Safety and Substantial Equivalence:

A series of non-clinical tests and a clinical study were performed to demonstrate the substantial equivalence of the device to the predicate device. All testing was conducted in accordance with the May 1994 FDA guideline titled *Premarket Notification 510(k) Guidance Document for Class II Contact Lenses* and in conformance to applicable device regulations. Results verify that the modified nelfilcon A lenses have material characteristics comparable to the predicate nelfilcon A soft contact lenses and are non-toxic and biocompatible. Clinically, the lens performed satisfactorily in a daily disposable wear investigation. Results from all tests demonstrate the substantial equivalence to previously FDA cleared predicate (control) lenses.

Non-clinical Testing:

A series of non-clinical testing was performed to verify equivalence of the device to the predicate device. Non-clinical biocompatibility testing was conducted in accordance with the GLP regulation (21 CFR Part 58).

The results of all non-clinical testing on (nelfilcon A) contact lens demonstrate:

- Lens physical and material properties of the device are substantially equivalent to the predicate lens.
- The lens material and extracts of the device are substantially equivalent to the predicate device and are non toxic and non-irritating.

Clinical Testing:

The CIBA Vision® (nelfilcon A) contact lens was investigated in a clinical study for daily disposable wear. The clinical evaluation was conducted in accordance with current Good Clinical Practices and published regulations (21 CFR Parts 50, 56, 312, and 812). The study assessed the clinical performance of the lenses as compared to an FDA cleared and commercially available contact lens.

Clinical evaluation of the CIBA Vision® (nelfilcon A) lens demonstrated similar overall performance in the clinically relevant areas of vision, health, comfort and fit as compared to the control lens when used under daily disposable wear conditions.

Substantial Equivalence:

The CIBA Vision® (nelfilcon A) contact lens is substantially equivalent to the predicate lens and similar to other daily wear soft contact lenses in terms of water content (69% water) and ionic characteristics (FDA Group II: high water, nonionic), clinical performance, and indications for use.

Any differences which may exist between the CIBA Vision® (nelfilcon A) soft contact lens and other Group II soft hydrophilic contact lenses do not adversely affect the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2008

CIBA Vision Corporation
c/o Martina Heim, Ph.D., RAC
Senior Regulatory Specialist
11460 Johns Creek Parkway
Duluth, GA 30097

Re: K072777
Trade/Device Name: CIBA Vision® (nelfilcon A) One-Day Soft Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: December 21, 2007
Received: December 26, 2007

Dear Dr. Heim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

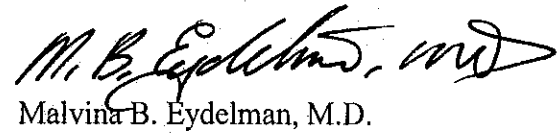
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PART III. INDICATIONS FOR USE STATEMENT

510(k) Number: K072777

Device Name: **CIBA Vision® (nelfilcon A) Soft Contact Lenses**

Indications For Use:

CIBA Vision® (nelfilcon A) Spherical and Toric One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Chandramallika Ghosh

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K072777

Prescription Use: ☒ **or** **Over the Counter Use** ☐